

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

*MD* Display Date 12-4-02  
Publication Date 12-5-02  
Certifier R. W. DESMA

New Animal Drugs for Use in Animal Feeds; Salinomycin and Tylosin  
Phosphate

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of approved, single-ingredient salinomycin and tylosin phosphate Type A medicated articles to make two-way combination Type C medicated feeds used as an aid in the prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency in broiler chickens.

**DATES:** This rule is effective [*insert date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600, e-mail: candres@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-198 that provides for use of BIO-COX (30 or 60 grams per pound (g/lb) salinomycin activity) and TYLAN (10, 40, or 100 g/lb tylosin phosphate) Type A medicated articles to make two-way combination Type C medicated broiler chicken feeds. The combination Type C medicated feeds contain 40 to 60 g/ton salinomycin

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**NADA 141-198**

**NFR**

and 4 to 50 g/ton tylosin phosphate and are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of September 4, 2002, and the regulations in 21 CFR 558.550 and 558.625 are being amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

#### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

1. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

2. Section 558.550 is amended by adding paragraph (d)(1)(xxii) to read as follows:

**§ 558.550 Salinomycin.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(xxii) *Amount per ton.* Salinomycin, 40 to 60 grams; plus tylosin, 4 to 50 grams.

(A) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

(B) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Do not feed to laying hens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin as provided by 046573; tylosin phosphate as provided by 000986 in § 510.600(c) of this chapter.

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3. Section 558.625 is amended by adding paragraph (f)(2)(viii) to read as follows:

**§ 558.625 Tylosin.**

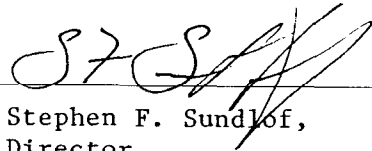
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(f) \* \* \*

(2) \* \* \*

(viii) Salinomycin as in § 558.550.

Dated: 11/21/02  
November 21, 2002



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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